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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/942, 369 10/02/97 CHEN

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EXAMINER

MORAN, M

ART UNIT	PAPER NUMBER
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1631

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DATE MAILED:

09/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/942,369	Applicant(s) Chen et al
	Examiner Marjorie Moran	Group Art Unit 1631

Responsive to communication(s) filed on Apr 10, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 20-24 and 26 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 20-24 and 26 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1631

This office action is supplemental to the office action mailed 7/5/00. In view of the new grounds of rejection set forth below, the time period for response to both this office action and the office action of 7/5/00 is hereby reset to start from the mailing date of this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejections not repeated below are hereby withdrawn. The following paragraph was inadvertently omitted from the office action of 7/5/00. For completeness, the paragraph is included in this office action with new rejections. The examiner regrets any confusion caused by the omission.

In view of the appeal brief filed on 4/10/00, PROSECUTION IS HEREBY REOPENED.
New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (b) request reinstatement of the appeal.

Art Unit: 1631

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 103

Claims 20-24 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (F) in view of LIBMAN *et al.* (H) and the MANUAL OF CLINICAL MICROBIOLOGY (MCB, reference I).

Applicant's arguments with respect to claims 20-25 and 27-30 have been considered but are moot in view of the new ground(s) of rejection. The arguments presented in the appeal brief of 4/10/00 are addressed below.

Applicant claims a method of simultaneously detecting urinary pathogens in a biological sample and determining susceptibility of the pathogens to antimicrobial agents wherein portions of a biological sample are separately added to compartments of an assay device which comprise, separately, a medium capable of sustaining growth of total microbial organisms, a uropathogenic specific medium, and an antimicrobial susceptibility interpretation medium, then examining the different compartments to determine presence and susceptibility of the urinary pathogens. In claim 21, applicant limits his biological sample to urine. In claims 22-23, he limits the pathogens to primary gram negative urinary pathogens, specifically Enterobacteriaceae. In claims 24-25, applicant limits his pathogens to specific species. It is noted that the specification, on page 10,

Art Unit: 1631

defines primary gram negative urinary pathogens as those which cause 85-90% of all urinary tract infections, which pathogens include but are not limited to *E. coli*, *Klebsiella* spp., *Enterobacter* spp., and *Proteus mirabilis*. It is further noted that the specification, on page 12, defines a uropathogen specific medium as one which allows only the growth of primary gram negative urinary pathogens and allows for substantially less growth of any other bacteria.

JOHNSON teaches a process (method) for detecting and determining the susceptibility of specific microorganisms to antibiotics wherein a clinical (urine) sample is added to separate wells of a microtiter plate, which wells comprise a selective culture medium or blends of the selective culture medium and known antibiotics, the plate is cultured, then the wells examined for growth of microorganisms (col. 10, line 45-col. 12, line 2 and col. 7, lines 33-36).

JOHNSON further teaches that his method and device may be used to analyze urinary pathogens, specifically *Escherichia coli*, *Klebsiella*, *Enterobacter*, and *Proteus* spp. (col. 3, lines 31-36).

JOHNSON also teaches that his sample may be urine, blood or spinal fluid, and that growth in individual growth wells permits a positive test for indication of organisms (col. 7, lines 39-46).

JOHNSON does not specifically teach a medium capable of sustaining growth of total microbial organisms.

LIBMAN teaches a device and method for detecting contaminating microorganisms (pathogens) in a urine sample wherein the sample is cultured on two or more different media, selective and nonselective (col. 3, lines 64-67). LIBMAN teaches that his selective media are "well-known differential media" and are "ideal for enumerating and presumptively identifying

Art Unit: 1631

urinary flora", and further teaches that common gram negative organisms (responsible *for more than 90% of urinary tract infections*) can be identified readily with his selective media (emphasis added by the examiner, col. 4, lines 1-15).

The MCB teaches use of selective media in identifying Enterobacteriaceae; e.g. in urine samples, and specifically teaches that MacConkey agar allows growth of gram-negative organisms while inhibiting gram-positive bacteria (see pages 264-265 and 1041).

It would have been obvious to one of ordinary skill in the art at the time of invention to include the nonselective medium of LIBMAN in the method of JOHNSON where the motivation would have been to provide a positive control for microorganismal growth, as suggested by JOHNSON. It would further have been obvious to detect gram negative organisms responsible for more than 90% of UTI's in the method of JOHNSON using the selective media taught by LIBMAN where the motivation would have been to determine the presence (and susceptibility) of the majority of microorganisms known to contribute to or cause UTI's in order to identify the causative organisms and to determine an appropriate course of treatment, as suggested by both LIBMAN (col. 2, lines 48-53) and JOHNSON (col. 3, lines 30-39). One skilled in the art would reasonably have expected success in incorporating the selective and nonselective media of LIBMAN in the method of JOHNSON because JOHNSON teaches sustenance of growth of total microbial organisms, which implies use of a nonselective medium, and because JOHNSON specifically teaches use of selective media. One skilled in the art would also have reasonably expected success in using the MacConkey agar of LIBMAN as a selective medium in the method

Art Unit: 1631

of JOHNSON because the MCB provides support for how to make MacConkey agar (p. 1074) and provides support that MacConkey agar is selective for gram-negative organisms (including those defined by applicant to be "gram negative urinary pathogens") over other any other bacteria, as set forth above.

In response to the argument that the prior art does not teach a "uropathogenic specific medium", as defined in the specification, the examiner points to the teaching of LIBMAN, above, for "selective media" which can be used to readily identify "gram negative organisms" responsible for "more than 90% of urinary tract infections" and the teachings of the MCB that MacConkey agar can be used to grow and identify Enterobacteriaceae from urine specimens. Although LIBMAN does not use the terms "uropathogen" or "uropathogenic specific medium", his definition of gram negative organisms which are responsible for more than 90% of UTI's is clearly congruent with applicant's definition for uropathogens, therefore a "specific medium" for growth of such organisms is a "uropathogenic specific medium". It is noted that applicant further defines his medium on page 13 of the appeal brief as one which selects against non-primary gram negative bacteria such as Bacteroides, Neisseria, etc. A teaching for a specific medium which inhibits or prevents the growth of bacteria other than primary gram negative bacteria is found in the originally filed specification on page 12; however, no teaching or recitation is found in the original specification or claims for specific exclusion of *gram negative* bacteria which are not primary gram negative uropathogens, nor is any exclusion of particular organisms recited anywhere. It is further noted that LIBMAN does teach that his device may be

Art Unit: 1631

used to detect *Neisseria* (col. 1, lines 56-63); however, LIBMAN teaches that the "selective media" for use in detecting *Neisseria* (e.g. a gonococcal medium) is different from those taught as selective media for detection of his gram negative organisms (col. 4, lines 44-53). Applicant further argues on page 15 of the appeal brief that the prior art does not elucidate (teach or make obvious) a medium containing multiple antibiotics which selects for multiple organisms, as set forth on page 19 of the specification. The claims do not recite antibiotics in a selective medium. The claims do not recite any limitations to the medium at all with regard to its composition. As set forth in the Advisory Action of 7/21/99, applicant was invited to amend the claims to add limitations regarding antibiotics, etc. in the selective medium in order to overcome the prior art then of record; however, no such amendments were filed. Applicant also argues that his method may be used with nonsterile urine samples. Both JOHNSON (col. 7, lines 33-50) and LIBMAN (col. 4, lines 54-64) teach detection of pathogens in nonsterile urine samples. The MCB also does not teach sterile samples.

For all of the reasons set forth above, claims 20-24 are obvious.

Claim 26 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON (F) in view of LIBMAN *et al.* (H) and the MCB (I) as applied to claim 20 above, and further in view of BROCCO (E).

Applicant's arguments with respect to claim 26 have been considered but are moot in view of the new ground(s) of rejection. All previous arguments with respect to claim 26 have

Art Unit: 1631

been addressed in previous office actions; no further arguments regarding claim 26 were set forth in the appeal brief of 4/10/00.

Applicant claims a method of simultaneously detecting urinary pathogens in a biological sample and determining susceptibility of the pathogens to antimicrobial agents, as set forth above. Applicant further limits the antimicrobial agents to amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

JOHNSON in view of LIBMAN and the MCB make obvious a method of simultaneously detecting target microorganisms in a biological sample and determining susceptibility of the microorganisms to antimicrobial agents using a nonspecific medium and a medium specific for urinary gram negative pathogens, as set forth above. JOHNSON in view of LIBMAN do not specifically teach amoxicillin, clavulanic acid/amoxicillin, or enrofloxacin.

As previously set forth in the office action of 11/9/98, BROCCO teaches a method of determining susceptibility of uropathogens, specifically *Staphylococcus* and *Streptococcus*, to amoxicillin and a clavulanic acid mixture (p. 5, line 8-p. 6, line 7 and p. 9, line 4-p. 10, line 15).

It would have been obvious at the time of invention to include the amoxicillin and clavulanic acid of BROCCO as antimicrobial agents in the method of JOHNSON in view of LIBMAN where the motivation would have been to test susceptibility of microorganisms, specifically urinary pathogens, to any known antibiotics, as suggested by JOHNSON, in order to determine an appropriate course of treatment for a subject infected with the microorganisms. For these reasons, claim 26 is obvious.

Art Unit: 1631

Conclusion

Claims 20-24 and 26 are newly rejected. The time period for response has been reset.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

ma
Marjorie A. Moran
Patent Examiner
Art Unit 1631

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